

☐ FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (MODIFIED)

ATTORNEY'S DOCKET NUMBER  
X16270M

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (if known; see 37 C.F.R. 1.5)

**10/553163**

INTERNATIONAL APPLICATION NO.  
**PCT/US2004/010960**

INTERNATIONAL FILING  
DATE 22 Apr 2004  
**22.04.2004**


PRIORITY DATE CLAIMED  
29 Apr 2003  
**29.04.2003**

**TITLE OF INVENTION: INSULIN ANALOGS HAVING PROTRACTED TIME ACTION**

**APPLICANT(S) FOR DO/EO/US: DIMARCHI Richard Dennis, KOHN Wayne David, and ZHANG Lianshan**

Applicant herewith submits to the U.S. Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
  2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
  3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
  4. ☒ The US has been elected (Article 31).
  5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
    - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
    - b. ☐ has been transmitted by the International Bureau.
    - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
  6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
  7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
    - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
    - b. ☐ have been transmitted by the International Bureau.
    - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
    - d. ☒ have not been made and will not be made.
  8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
  9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
  10. ☐ A declaration of the inventors 35 U.S.C. 371(c)(4) was provided in the PCT Request Form.
  11. ☐ A copy of the International Preliminary Examination Report (IPER), including any annexes, and, if not in English, an English language translation of the annexes to the IPER under PCT Article 36 (35 U.S.C. 371(c)(5)).
- Items 12. to 18. below concern document(s) or information included:**
12. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98. ☒ Search Report from ISA/EP
  13. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
  14. ☐ Assignment has been recorded at reel \_\_\_\_\_, frame \_\_\_\_\_.
  15. ☒ A **FIRST** preliminary amendment.  
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
  16. ☒ A Sequence Listing, 1.821 Statement, and diskette.
  17. ☒ A power of attorney with attachment (37CFR 3.73(b)).
  18. ☒ Other items or information:  
Please amend the first page of the specification by inserting the following cross-reference after the title: "This is the national phase application, under 35 USC 371, for PCT/US2004/010960, filed 22 April 2004, which, claims the benefit, under 35 USC 119(e), of US provisional application 60/466,501, filed 29 April 2003, of US provisional application 60/466,500, filed 29 April 2003, and of US provisional application 60/470,118, filed 13 May 2003."

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
<b>10/553163</b>		<b>PCT/US2004/010960</b>		<b>X16270M</b>	
19.	<b>X</b>	The following fees are submitted:		<b>CALCULATIONS PTO USE ONLY</b>	
(a)	Basic national fee (37 CFR 1.492(a)).....\$300.00			\$	
(b)	Examination fee (37 CFR 1.492(c))  If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0 All other situations.....\$200			\$	
(c)	Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0  Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100  International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....\$400  All other situations.....\$500			\$400.00	
<b>TOTAL AMOUNT (a + b + c) =</b>				<b>\$400.00</b>	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS		NUMBER FILED	NUMBER EXTRA	RATE	
Total claims		20-20=	0	X \$50.00	\$
Independent claims		1-3=	0	X \$200.00	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$360.00	\$360.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$</b>	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$	
<b>SUBTOTAL =</b>				<b>\$360.00</b>	
Processing fee of \$130.00 for furnishing English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
<b>TOTAL NATIONAL FEE =</b>				<b>\$760.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).				\$	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$760.00</b>	
				Amount to be refunded	\$
				charged	\$
a.	<input type="checkbox"/>	A check in the amount of \$_____ to cover the above fees is enclosed.			
b.	<input checked="" type="checkbox"/>	Please charge my Deposit Account No. 05-0840 in the amount of <u>\$760.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.			
c.	<input checked="" type="checkbox"/>	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 05-0840. A duplicate copy of this sheet is enclosed.			
<b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>					
SEND ALL CORRESPONDENCE TO: ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, INDIANA 46206-6288 <i>Oct 22 13, 2005</i> Date 41,264 REGISTRATION NUMBER		SIGNATURE <i>Grant E. Reed</i> 317-278-1664 TELEPHONE NUMBER		 <b>25885</b> PATENT TRADEMARK OFFICE	

IN THE UNITED STATES RECEIVING OFFICE (USRO)

Applicant(s): Richard Dennis DIMARCHI  
Wayne David KOHN  
Lianshan ZHANG

International Application No.: PCT/US2004/010960  
Filed: 22 April 2004 (22.04.04)  
Invention: INSULIN ANALOGS HAVING PROTRACTED TIME ACTION  
Lilly Reference: X-16270M  
Earliest Priority Date: 29 April 2003 (29.04.03)

**Certificate Under 37 C.F.R. § 1.10**

Attention: DO/EO  
Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

"Express Mail" mailing label number: EV 393128209 US  
Date of Deposit: Oct. 13, 2005

I hereby certify that the following attached paper or fee

Transmittal Letter to the United States Designated/Elected Office (US) concerning a filing under 35 U.S.C. 371 of the International Application identified above is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

QUEEN THOMAS  
(Typed or printed name of person mailing paper)

Queen Thomas  
(Signature of person mailing paper or fee)

**CERTIFICATE UNDER 37 CFR 3.73(b)** JC20 Rec'd PCT/PTO 13 OCT 2005

Applicant: Richard Dennis DIMARCHI, et al.

Application No.: US Nat'l Phase of PCT/US2004/010960 Filed: \_\_\_\_\_

Entitled: INSULIN ANALOGS HAVING PROTRACTED TIME ACTION

ELI LILLY AND COMPANY

(Name of Assignee)

, a CORPORATION

(Type of Assignee, e.g. corporation, partnership, university, government agency, etc.)

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application identified above.

☐ The assignment was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_.

☒ The assignment is being submitted separately for recordation; a copy of this assignment is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From: \_\_\_\_\_ To: \_\_\_\_\_

The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

2. From: \_\_\_\_\_ To: \_\_\_\_\_

The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

3. From: \_\_\_\_\_ To: \_\_\_\_\_

The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date

October 13, 2005

Grant E. Reed  
Patent Attorney